

## **REMARKS**

In the Official Action dated December 24, 2003, Claims 1-8 have been rejected under 35 U.S.C. §112 as allegedly indefinite. Claims 1, and 3-8 have been rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention.

This response addresses each of the Examiner's objections and rejections. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 1, and 3-8 are being amended in this response for the sole purpose of expediting prosecution. New Claims 9-12 have been added. No new matter has been added, no narrowing amendments have been made, and no amendments have been made in view of prior art. Entry of this amendment is respectfully requested.

The Examiner has rejected Claims 1-8 under 35 U.S.C. §112 as allegedly indefinite. The Examiner has made the following objections in this regard:

1. The Examiner alleges that the terms "preferably" and "eg" are improper. Applicants have deleted the terms "preferably" and "eg" from the claims for the sole purpose of expediting prosecution and for favorable consideration of the claims. This amendment therefore renders this objection moot.

2. The Examiner alleges that the term "containing" in the R<sup>2</sup>-R<sup>5</sup> definitions is open ended and should be replaced by the term "having." Applicants have replaced the term "containing" in the R<sup>2</sup>-R<sup>5</sup> definitions with the term "having." for the sole purpose of expediting prosecution and for favorable consideration of the claims. This amendment therefore renders this objection moot.

3. The Examiner alleges that there are species in claim 4 that are outside the scope of claim 1. The Examiner questioned whether term "hydroxyalkyl" was in the definition of R<sup>1</sup> in claim 1. The Examiner also alleges that the 3<sup>rd</sup> species in claim 4 is not a heteroaryl, and the 4<sup>th</sup> and 5<sup>th</sup> species are not within the scope of C<sub>1</sub>-C<sub>6</sub> alkyl in claim 1.

In view of amending claim 4 to independent form, this rejection is rendered moot. Applicants however respectfully point out that “hydroxyalkyl” is within the scope of the definition of R<sup>1</sup> in claim 1. R<sup>1</sup> can be C<sub>1</sub>-C<sub>6</sub> alkyl which can be substituted by hydroxy. In regard to the 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> species in claim 4, applicants observe that these species are covered in claim 1. The 3<sup>rd</sup> species in claim 4 has a methyl group at the R<sup>1</sup> position, which is covered by C<sub>1</sub>-C<sub>6</sub> alkyl. The 4<sup>th</sup> and 5<sup>th</sup> species in claim 4 has ethyl and benzyl groups at the R<sup>1</sup> position, which are covered by C<sub>1</sub>-C<sub>6</sub> alkyl and arylmethyl respectively.

4. The Examiner objects to composition claims 5 and 7 as being substantial duplicates. Applicants maintain that the pharmaceutical compositions of claims 5 and 7 are distinct. Specifically, claim 5 relates to a pharmaceutical composition comprising an amount of a compound according to claim 1 that is effective in treating the disorders listed in the claim. In contrast, claim 7 relates to a pharmaceutical composition comprising a serotonin 7 receptor antagonizing amount of a compound according to claim 1. Claims 5 and 7 differ because the composition in each claim is defined by its ability to be effective in a separate mechanism of action. A pharmaceutical composition comprising an amount of a compound according to claim 1 that is effective in treating the disorders listed in the claim can differ in the ingredients contained therein from a pharmaceutical composition comprising a serotonin 7 receptor antagonizing amount of a compound according to claim 1.

5. The Examiner objects to composition claims 6 and 8 as being substantial duplicates. Applicants maintain that the pharmaceutical compositions of claims 6 and 8 are distinct for the same reasons claims 5 and 7 are distinct. A method of treating a disorder with a pharmaceutical composition comprising an amount of a compound according to claim 1 that is effective in treating the disorders listed in the claim can differ in the ingredients contained therein from a pharmaceutical composition comprising a serotonin 7 receptor antagonizing amount of a compound according to claim 1.

The Examiner has rejected Claims 1-8 under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling disclosure.

In response, Applicants respectfully submit that pending claims 1-8 were enabled at the time the present application was filed.

Applicants respectfully submit that sufficient direction and guidance to practice the claimed invention is disclosed throughout the specification as follows:

Page 7, paragraphs 94-97 and page 8, paragraphs 98-122, disclose, as an example, how to measure the affinities of the claimed compounds for serotonin 7 receptors.

Page 8, paragraph 123, discloses how measure the 5HT7 IC<sub>50</sub> values for the claimed compounds.

Page 8, paragraphs 124-136 and page 9, lines 139-140, disclose how to evaluate the claimed compounds at 5HT7 receptors.

Page 8, paragraph 142, discloses how to determine the activity of the active compounds as antidepressants and related pharmacological properties.

Applicants respectfully submit that based on the above disclosures in the present application, no undue experimentation is required to determine the utility and activity of the claimed compounds as antidepressants and related pharmacological properties. A considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Accordingly, the present application provides sufficient direction and guidance to the skilled artisan to practice the invention as claimed. In re Wands, 858 F.2d 731, 736-737, 8 U.S.P.Q. 1400, 1404 (Fed Cir. 1988). Necessary experimentation is not determinative of the question of enablement; only undue experimentation is fatal under the provisions of 35 U.S.C. §112, first paragraph. Id.

The Examiner also alleges that compounds having the ability to antagonize 5HT7 receptor sites are not necessarily enabling for the treatment of diseases listed in the claims. Applicants respectfully submit that it is known in the art that the clinical significance of compounds that have the ability to antagonize 5HT7 receptor sites is enabling for the treatment of diseases listed in the claims. See page 21 Glennon et al., Serotonin Receptor Subtypes and Ligands, <http://www.acnp.org/G4/GN401000039/Ch039.html>. (Exhibit A) See also 5HT7: Pharmaceutical opportunities in the fields of CNS and cardiovascular diseases.

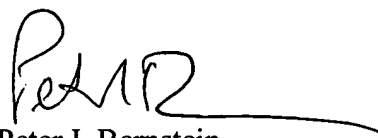
[http://www.bioportfolio.com/news/leaddiscovery\\_20.htm](http://www.bioportfolio.com/news/leaddiscovery_20.htm). (Exhibit B) Copies of these articles are enclosed herein for the Examiner's convenience.

Therefore, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

Finally, applicants have amended the specification to provide a cross reference to related applications.

Thus, in view of the foregoing amendments and remarks, the application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Peter I. Bernstein', with a long horizontal flourish extending to the right.

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Registration No. 43,497

PIB/RLB:nis  
Enclosures